DEPARTMENT OF HEALTH & HUMAN SERVICES

PMS File

Public Health Service

P930012

Memorandum

Date SEP 27 1995

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Progressive Angioplasty Systems, Inc.
PAS LaCrosse™ PTCA Catheter - ACTION

To The Director, CDRH
Through: ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by: Tara A. Ryan, CDRH, HFZ-450, 9/11/95, 443-8243

ORIGINAL ACTION MEMO (OACTM) Modified: 8-15-94

Prepared by:swf:9/11/95

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO.]

PROGRESSIVE ANGIOPLASTY SYSTEMS, INC.; PREMARKET APPROVAL OF THE PAS LACROSSE™ PTCA CATHETER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Progressive Angioplasty Systems, Inc., Menlo Park, CA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the PAS LaCrosse™ PTCA Catheter.

DATE: Petitions for administrative review by (insert date 30 days after date of Publication in the FEDERAL REGISTER) ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Veronica Price

Center for Devices and Radiological Health (HFZ-450)

Food and Drug Administration

9200 Corporate Boulevard

Rockville, Maryland 20850

301-443-8243.

SUPPLEMENTARY INFORMATION: On April 4, 1994, Progressive Angioplasty Systems, Inc., Menlo Park, CA 94025-1516, submitted to CDRH an application for premarket approval of the PAS LaCrosse™ PTCA Catheter. The device is a percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter and is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel.

On SEP 2 7, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition,

under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the act section 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Catherine Diez-Luckie
Chief Operating Officer
Progressive Angioplasty Systems, Inc.
1350 Willow Road, Suite 201
Menlo Park, California 94025-1516

SEP 27 1995

Re: P930012
PAS LaCrosse™ PTCA Catheter
Filed: April 4, 1994
Amended: February 8, May 30, July 17, August 16, 24, and 28, September 8 and 13, 1995

Dear Ms. Diez-Luckie:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the PAS LaCrosse™ PTCA Catheter (2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm and 4.0 mm). This device is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at two years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).]

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Veronica Price at (301) 443-8243.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

Device Generic Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter

Device Trade Name: PAS LaCrosse™ PTCA Catheter

Applicant's Name & Address: Progressive Angioplasty Systems, Inc.
1350 Willow Road Suite 201
Menlo Park, CA 94025

PMA Number: P930012

Date of Notice of Approval to Applicant: SEP 27 1995

II. Indications

The PAS LaCrosse™ PTCA Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

III. Device Description

The PAS LaCrosse™ PTCA Catheter is a double lumen coaxial catheter with a balloon near the distal tip. The catheter is constructed from two coaxially aligned tubings. The first (inner) lumen is made of a polyvinylidene fluoride (PVDF) polymer. The second (outer) lumen is composed of two tubings joined together. The proximal tubing is made of polyvinylidene fluoride (PVDF) and is joined to a polyolefin (distal) tubing. The distal portion of the polyolefin tubing has a non-elastomeric balloon formed in it. The balloon is designed to expand to a controlled diameter and length at a specific pressure. The distal end of the balloon is attached to the inner lumen with an adhesive joint. The inner member provides a through lumen for guide wire movement. The LaCrosse™ Catheter does not provide for distal dye injection or pressure measurement.

As with other removable guide wire systems, a side-arm adapter attached to the proximal end of the catheter provides access to the lumens. The side port provides access to the outer balloon inflation lumen by means of a luer-lock fitting. Balloon inflation and deflation are accomplished by connecting the side-arm port with an inflation device. The straight-arm port is continuous with the inner lumen of the catheter and provides access for the guide wire. The catheter is available in five dilatation balloon sizes: nominally 2.0, 2.5, 3.0, 3.5 and 4.0mm. The LaCrosse™ Catheter can be used with any off-the-shelf 0.014 PTCA guide wires.

IV. Contraindications

The PAS LaCrosse™ PTCA Catheter is contraindicated in patients with:

- Unprotected left main coronary artery.

- Coronary artery spasm in the absence of a significant stenosis.

V. Warnings

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the: "Use Before" date specified on the package.

VI. Precautions

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

- Administer appropriate anticoagulant and coronary vasodilator therapy before inserting the dilatation catheter.

VII. Alternative Practices and Procedures

Alternative treatments for coronary artery disease are medical therapy, coronary atherectomy, coronary laser, coronary stent, coronary endarterectomy and coronary artery bypass graft (CABG) surgery.

VIII. Marketing History

The PAS LaCrosse™ PTCA Catheter has not been previously marketed in the United States.

The PAS LaCrosse™ PTCA Catheter has been marketed in Germany, Japan, Holland, Canada, and France.

The device has not been removed from any market for reasons of safety and effectiveness.

IX. Adverse Events

The table listed below outlines the adverse events which occurred during the clinical trial:

	n	%
Myocardial Infarction		
Q wave	1	0.6
non Q-wave	3	1.8
CABG	1	0.6
Transient closure	3	1.8
Embolus	1	0.6
Out of lab occlusion	1	0.6
Repeat PTCA	2	1.2
Major dissection	5	3.1
Congestive Heart Failure	2	1.2
Atrial fibrillation	1	0.6
Recurrent angina	1	0.6
GI bleed	1	0.6
Pseudoaneurysm of groin	0	0

Other historically reported potential adverse events associated with PTCA are:

hematoma
drug reactions, allergic reaction to contrast medium
hypo/hypertension

Other historically reported potential adverse events associated with PTCA are:

hematoma
drug reactions, allergic reaction to contrast medium
hypo/hypertension
infection
coronary artery spasm
arteriovenous fistula

X. Summary of Studies

A. In-Vitro (Laboratory) Studies

1. Biocompatibility and Toxicology Testing

Biological assay testing indicated that the tissue-contacting materials of the PAS LaCrosse™ PTCA Catheter were biocompatible and non-toxic. The biological assays conducted include acute systemic toxicity, intracutaneous toxicity, implantation, hemolysis, acute cytotoxicity, dermal sensitization, thrombogenicity and mutagenicity.

2. Microbiology Testing

The PAS LaCrosse™ PTCA Catheter was subjected to an ethylene oxide process to assure sterility according to the "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices" by the Association for the Advancement of Medical Instrumentation (AAMI). The sterility assurance level (SAL) is 10^{-6}. Results of testing validated the sterilization cycle. Samples of the PAS LaCrosse™ PTCA Catheter were tested after aeration to determine if ethylene oxide, ethylene chlorohydrin or ethylene glycol were present. All residual levels were below the maximum residual limits as specified in the Federal Register 43, June 23, 1978.

3. Balloon Minimum Burst Strength Testing

The purpose of this test was to demonstrate that the minimum burst strength of the balloons are adequate for the intended use and to determine appropriate rated burst pressures. One hundred samples, twenty of each balloon diameter, were inflated with increasing pressure until failure. The results demonstrated that with 95% confidence, 99.9% of the balloons will not burst at or below the rated burst pressure of 9 atm for the 2.0mm and 2.5mm; 8 atm for the 3.0mm and 3.5mm; 6 atm for the 4.0mm.

4. Balloon Distensibility Test

Measurements of the balloon diameter at various inflation pressures were made to determine the balloon compliance. Twenty catheters of each balloon size were tested. The following results were obtained: 2.0mm at 7 to 8 atm.; 2.5mm at 7 to 8 atm.; 3.0mm at 6 to 7 atm.; 3.5mm at 6 to 7 atm.; 4.0mm at 5 to 6 atm.

coronary artery. Using a 50/50 mixture of saline and contrast solution, all inflation times were below 3 seconds. All deflation times to the collapsed profile were measured at less than ten seconds.

6. Balloon Fatigue

Cycle testing was performed to determine the ability of the balloon to withstand repeated inflations to the labeled rated burst pressure. Each balloon was attached to the pressure cycle tester and immersed in a 37°C water bath. Each balloon was subjected to forty pressurizations to the labeled rated burst pressure or until the balloon failed. Thirty balloons of each diameter were tested, with no failures.

7. Profile Measurements

To determine the collapsed profile of the balloon in the clinical situation, profile measurements were performed on at least 5 test samples of each size. The balloon was deflated and passed through successively smaller holes until it no longer passed. The average deflated profiles for the five sizes were between 0.027 and 0.036 inches.

8. Pull and Bonding Test

To demonstrate the integrity of all joints of the PAS LaCrosse™ PTCA Catheter, tensile testing was performed on all adhesive/solvent joints in ten catheters, including the tip. Tests conducted included: inner member to funnel luer joint strength, PVDF shaft tubing to strain relief tubing joint strength, strain relief tubing to Y-Adapter joint strength, funnel luer to Y-Adapter joint strength, and distal balloon tip to inner member joint strength. All joints had a tensile strength of at least one pound.

9. Catheter Tip Integrity

Three tests were conducted to demonstrate catheter tip integrity:

a. Torque Strength Test. To demonstrate the torsional strength of the PAS LaCrosse™ PTCA Catheter, the tips of ten catheters were held and the bodies rotated at the proximal connector. It was not possible to induce failure of the tip in any catheters after one hundred rotations, though severe distortion of the catheter material was noted.

b. Pushability Test. The integrity of the tip was demonstrated by pushing ten catheters and deflecting them off of a flat plate. The catheters remained intact during testing.

c. Cycle/Flex Test. Ten catheters were constrained at the tip in a moving part of the test fixture, with the catheter shafts constrained in the stationary part of the fixture. The tips were then subject to 10,000 flexing cycles and remained intact in all catheters.

10. Inner Member Rupture Pressure

To verify the strength of the inner member, twenty inner members were pressurized internally up to a maximum pressure of 20 atms. None of the twenty inner members burst at or below 20 atms.

B. Animal Studies

The PAS LaCrosse™ PTCA Catheter was evaluated in-vivo to demonstrate that the catheter system would function safely and effectively in actual use in the coronary anatomy. Three dogs and one pig were used in the study. Standard 8 and 9 French guiding catheters were used to intubate the coronary arteries.

The experiments demonstrated acceptable wire motion, trackability and pushability of the catheter. Also, the gold band exhibited acceptable radiopaqueness during the experiments. Balloon inflations did not result in burst and there was adequate dye opacification of the coronary artery through the guide catheter and around the balloon catheter. No adverse effects were noted. There was no indication of thrombus in any of the animals or on any of the catheters after removal from the animals. Angiography on each of the cases revealed no evidence of dissection, thrombus or acute occlusion.

C. Summary of Clinical Studies

A multi-center nonrandomized prospective clinical investigation of the Progressive Angioplasty Systems (PAS) LaCrosse™ PTCA catheter was conducted to determine the safety and effectiveness of the device. The data were collected from 164 subjects (enrolled at 11 investigational sites (23 investigators)) between January 30, 1992 and March 7, 1994. The core population of patients consisted of 147 patients. This number reflects the total population of 168 patients minus patients where no LaCrosse™ PTCA Catheter inventory existed or where the LaCrosse™ PTCA Catheter was used second.

Patients considered candidates for this study were males and females older than 18 years with discrete, subtotal, non-calcified lesions of the left anterior descending, circumflex or right coronary arteries or coronary artery bypass grafts. Patients had symptomatic coronary artery disease with indication for PTCA. Patients were excluded who had diffuse or calcified stenoses, documented coronary spasm, unprotected left main stenosis, totally obstructed coronary artery, inability to give informed consent or were not candidates for coronary artery bypass graft surgery (CABG).

1. Study Population

a. Demographic and Clinical Characteristics

Number of Procedures	164	
Mean Age (years)	63.9±10.5	
Gender (male)	116/164	70.7%
Current History of Smoking	31/164	18.9%
History of Diabetes	37/164	22.6%
Previous Infarction	69/164	42.1%
Previous CABG	40/164	24.4%
Previous PTCA	32/164	19.5%
Renal Disease	6/164	3.7%
High Risk	22/164	13.4%
Angina		
CHC Class 0-I	15/164	9.1%
II	26/164	15.9%
III	56/164	34.1%
IV	67/164	40.9%
Recent MI	22/164	13.4%
Vessel Disease		
Single	61/164	37.2%
Double	55/164	33.5%
Triple	48/164	29.3%
Ejection Fraction (%)		
<30%	11/164	6.7%
30-50%	44/164	26.8%
>50%	104/164	63.4%
Not available	5/164	3.0%

b. Vessel and Lesion Characteristics

i. Site angiographic review

		Range
Number of Lesions	228	
Reference Vessel Diameter (mm)	2.8±0.5	1.9-4.5
Lesion length (mm)	6.0±4.4	0.3-30.0
Percent Diameter Stenosis	86.4±12.7	45-100
Target Vessel*		
LAD	85/228	37.3%
RCA	67/228	29.4%
Lcx	47/228	20.6%
Grafts	23/228	10.1%

ACC/AHA lesion type		
A	84/228	36.8%
B	121/228	53.1%
C	23/228	10.1%
*not available on 6 lesions		

ii. Core Angiographic Data

		Range
Number of Lesions	140	
Reference Diameter (mm)	2.74±0.45	1.8-4.2
Minimum lumen diameter (mm)	0.67±0.33	0-7.8
Percent diameter stenosis	75.5±11.01	0.5-100
Lesion length (mm)	6.4±0.33	2.0-17.9
Target Vessel		
LAD	49/140	35.0%
RCA	40/140	28.6%
Lcx	37/140	26.4%
Grafts	13/140	9.3%
Left Main	1/140	0.7%
ACC/AHA lesion type		
A	39/140	27.9%
B	91/140	65.0%
C	10/140	7.1%
Lesion Morphology		
Concentric	42/140	30.0%
Eccentric	96/140	68.6%
Occluded	2/140	1.4%

2. Safety Data

a. Complications

During the investigation, the following complications were noted:

	In Hospital (N=164)			Post Discharge (N=145)		
	n	%	95% C.I.	n	%	95%C.I.
Death	0	0	0.00-1.81	0	0	0.00-2.04
Myocardial Infarction						
Q wave	1	0.6	0.02-3.35	0	0	0.00-2.04
non Q-wave	3	1.8	0.37-5.52	0	0	0.00-2.04
CABG	1	0.6	0.02-3.35	1	0.7	0.00-4.20
Transient closure	3	1.8	0.37-5.52	0	0	0.00-2.04
Embolus	1	0.6	0.02-3.35	0	0	0.00-2.04
Out of lab occlusion	1	0.6	0.02-3.35	0	0	0.00-2.04
Repeat PTCA	2	1.2	0.15-4.34	9	6.2	3.20-12.5
Major dissection	5	3.1	0.99-6.97	0	0	0.00-2.04
Perforation	0	0	0.00-1.81	0	0	0.00-2.04
Major Hematoma**	0	0	0.00-1.81	0	0	0.00-2.04
Renal Failure	0	0	0.00-1.81	0	0	0.00-2.04
Stroke	0	0	0.00-1.81	0	0	0.00-2.04
Congestive Heart Failure	2	1.2	0.02-3.35	0	0	0.00-2.04
Vascular occlusion	0	0	0.00-1.81	0	0	0.00-2.04
Atrial fibrillation	1	0.6	0.02-3.35	0	0	0.00-2.04
Balloon rupture	2	1.2*	0.15-4.34	0	0	0.00-2.04
Pericardial tamponade	0	0	0.00-1.81	0	0	0.00-2.04
Pulmonary edema	0	0	0.00-1.81	0	0	0.00-2.04
Recurrent angina	1	0.6	0.02-3.35	0	0	0.00-2.04
GI bleed	1	0.6	0.02-3.35	0	0	0.00-2.04
Pseudoaneurysm of groin	0	0	0.00-1.81	1	0.7	0.00-4.20
Total	24			11		
Any complication	24	14.6		11	7.6	
Patients free of any acute complications:		139/164	84.8%	95%		CI=79.3 - 89.9

*By patient

**Requiring surgical repair or blood transfusion

i. Major Cardiac Events

Major In-Hospital Cardiac Events

(N=164 patients)	n	%	95% C.I.
Death	0	0	0.00-1.81
Q MI	1	0.6	0.02-3.25
CABG	1	0.6	0.02-3.25
Repeat Intervention	2	1.2	0.15-4.34
Any Event	4	2.4	0.67-6.1

Major Out-of-Hospital Cardiac Events

(N=145 patients)	n	%	95% C.I.
Death	0	0	0.00-2.04
Q MI	0	0	0.00-2.04
CABG	1	0.7	0.02-3.78
Repeat Intervention	9	6.2	2.88-11.46
Any Event	10	6.9	3.36-12.32

ii. Deaths

There were no deaths in either the acute or follow-up component of the study.

b. Device Malfunction

There were 188 PAS LaCrosse™ catheters used in 164 procedures. A list of the device malfunctions that occurred during the study follows:

Dilatation Performance Malfunctions
(N=188 Catheters Used)

	n	%	95% C.I.
Balloon burst	2^	1.1	0.1-3.8
Poor wire motion	2	1.1	0.1-3.8
Y adaptor leak	0	0	0.0-1.6
Delayed inflation	0	0	0.0-1.6
Delayed deflation	0	0	0.0-1.6

^Both balloons burst at or above rated pressure.

There were no patient injuries related to device malfunctions.

3. Effectiveness Data

a. Definitions

Technical Success - All of the following must occur:

- The PTCA wire must cross the lesion.
- The LaCrosse™ PTCA Catheter must be used first.
- The LaCrosse™ PTCA Catheter must cross the lesion.
- There must be no mechanical failure.
- There must be no other device used due to any complication.

Clinical Success - All of the following must occur:

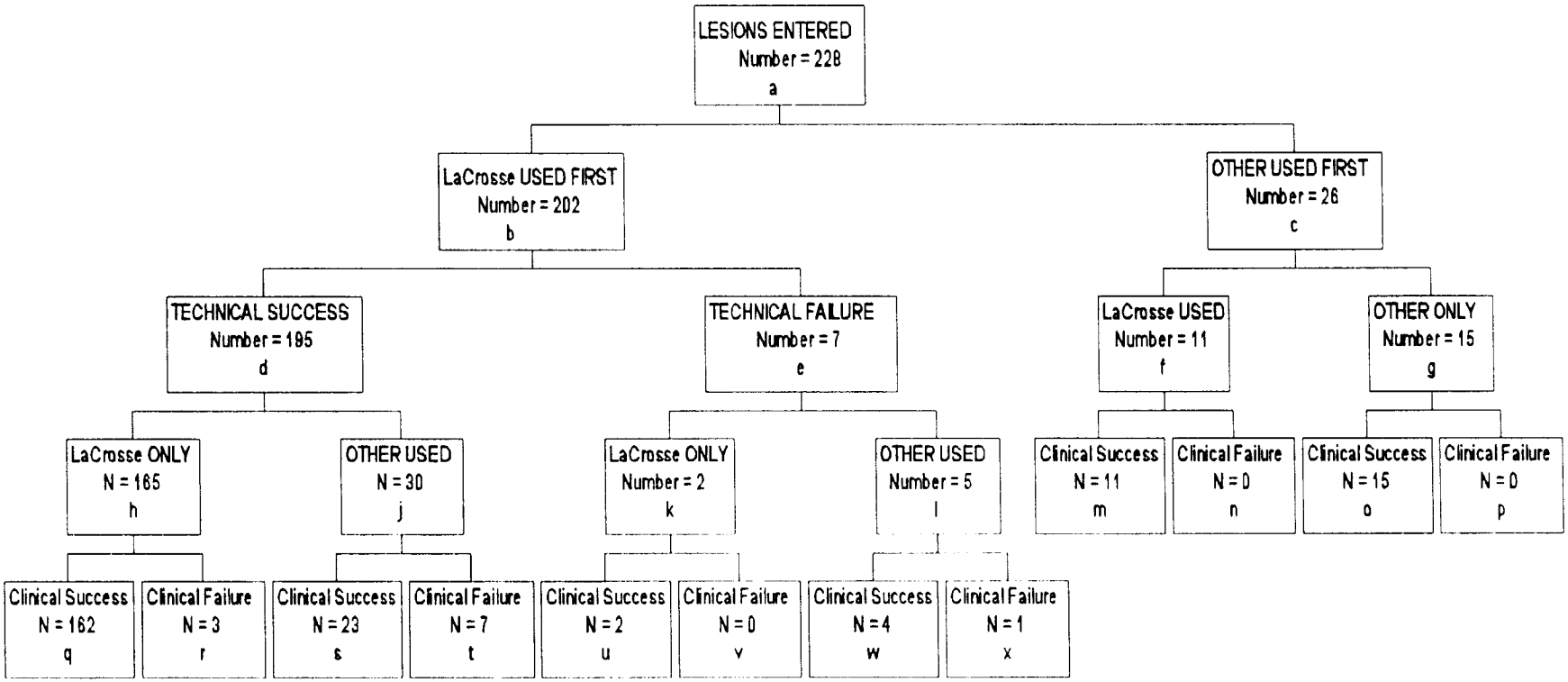
- A reduction in percent stenosis of ≥ 20%.
- A residual diameter stenosis of ≤ 50%.
- No acute patient complications, and no in-hospital reclosure, emergent reintervention, bailout stenting, myocardial infarction (Q wave or non-Q wave) or death.

Stand Alone Population: All patients treated exclusively with the PAS LaCrosse™ PTCA Catheter for all lesions. In calculating success rates, the denominator is all patients treated with the PAS LaCrosse™ PTCA Catheter first.

Total Population: All patients treated with the PAS LaCrosse™ PTCA Catheter.

Patient Success: All lesions successfully dilated to <50% maximum residual stenosis and an increase in luminal diameter of ≥ 20% with no major in-hospital ischemic complications (death, Q MI, or CABG).

b. Lesion Results Flow Chart



c. Clinical Success Rates

	Values for PAS LaCrosse™ PTCA		
	Value	(%)	95%C.I.
Lesions Treated Device First (q + s + u + w) / b	191/202	(94.6)	90.6-97.3
Lesions Treated Successfully (Technically and Clinically) Device First (q + s) / b	185/202	(91.6)	86.9-95.0
Acute Technical & Clinical Success For Lesions Treated with Device Only q / b	162/202	(80.2)	74.0-85.5

d. Details of Lesion Results Flow Chart

i. Other Devices Used First ("c" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed	23
Directional Coronary Atherectomy (DCA)	3
Total 26 lesions	

ii. Reasons for PAS LaCrosse™ PTCA Catheter failures ("e" on Lesion Results Flow Chart)

Balloon Rupture (over pressure)	2
Dissection requiring perfusion catheter	2
Transient closure requiring perfusion catheter	1
Q Myocardial Infarction	2
Total 7 lesions	

iii. Other Devices following PAS LaCrosse™ PTCA Catheter ("l" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed	5
Total 5 lesions	

iv. Other Devices following PAS LaCrosse™ PTCA Catheter ("j" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed	28

DCA	2
	Total 30 lesions

v. Reasons for PAS LaCrosse™ PTCA Catheter Clinical Failure ("r" on Lesion Results Flow Chart)

Wire/Catheter could not cross lesion	2
Clinical complication: Elective in-house CABG	1
	Total 3 lesions

e. Patient Accountability

There were 127 patients in which one or more lesions were attempted with the PAS LaCrosse™ PTCA Catheter only. There was at least one successfully treated lesion in 124 (97.6%). There were 122 patients in which all lesions were attempted with the PAS LaCrosse™ PTCA Catheter only. All lesions were successfully treated in 119 patients (97.5%).

	N	(%)	95% C.I.
One or More PAS LaCrosse™ Only Lesions	127		
One or More Lesions Successful	124	(97.6)	92.7-99.5
All PAS LaCrosse™ PTCA Lesions	122		
All Lesions Successful	119	(97.5)	92.7-99.5

f. Evaluation of Gender Bias

The patient population enrolled in this study was 70.0 percent male, a proportion similar to other recent interventional studies. Higher incidence rates of coronary artery disease in men have long been reported by in epidemiologic studies (Douglas, P.S. (ed): Cardiovascular Clinics 19:129-145). Acute success rates and complication rates did not differ significantly by patient gender:

i. Total Population

	N	(%)	95%C.I.
	Denom.: Male:	116	
	Denom.: Female:	48	
Procedure Success			
MALES	110	(94.8)	89.1-98.1
FEMALES	45	(93.8)	82.8-98.7
	p=0.722		
CABG/QMI/DEATH			
MALES	1	(0.8)	0.02-4.7
FEMALES	1	(2.0)	0.06-11.1
	p=0.504		

ii. Stand Alone Population (Gender Bias Analysis)

	N	(%)	95% C.I.
	Denom.: Male: 85		
	Denom.: Female: 37		
Procedure Success			
MALES	83	(97.6)	91.8-99.7
FEMALES	36	(97.3)	85.8-99.9
	p=1.000		
CABG/QMI/DEATH			
MALES	0	(0.0)	0.00-4.5
FEMALES	1	(2.7)	0.68-14.2
	p=0.301		

iii. PAS LaCrosse™ First Population

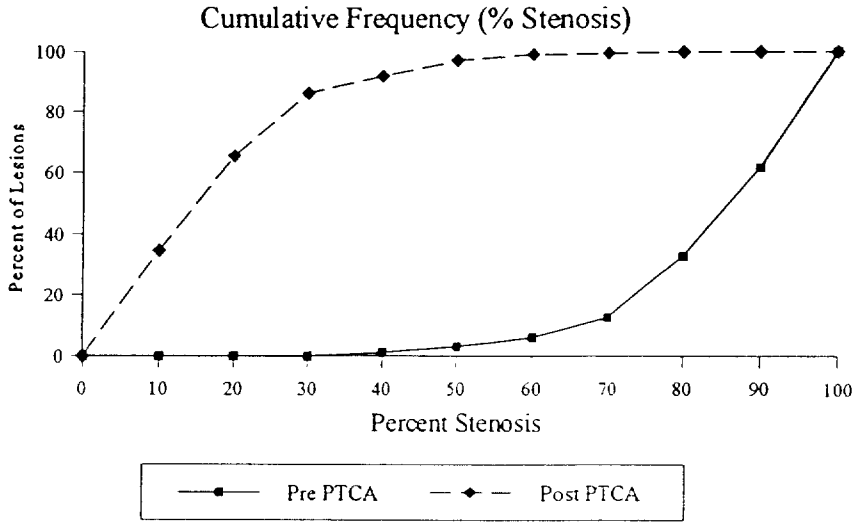
	N	(%)	95% C.I.
	Denom.: Male:	102	
	Denom.: Female:	45	
Procedure Success			
MALES	97	(95.1)	88.9-98.4
FEMALES	42	(93.3)	81.7-98.6
	p=0.700		
CABG/QMI/DEATH			
MALES	1	(1.0)	0.02-5.3
FEMALES	1	(2.2)	0.06-11.8
	p=0.517		

g. Acute Angiographic Results

The angiographic data for lesions treated with the PAS LaCrosse™ PTCA catheter in this investigation, both prior to and following PTCA are summarized below. Both Site Data and Core Lab Data for the Total Population are presented:

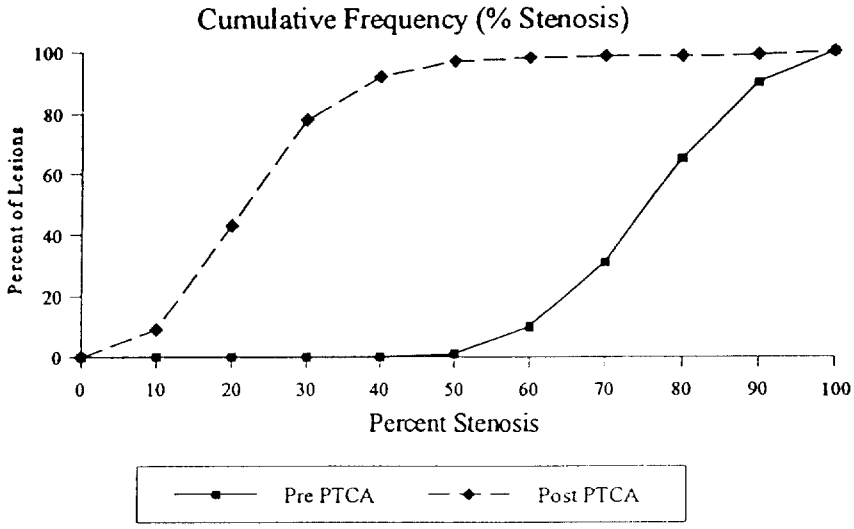
i. Cumulative Frequency Curve (Percent Stenosis), Site Data, Total Population Lesions (N=228).

SITE DATA - TOTAL POPULATION LESIONS (N=228)



ii. Cumulative Frequency Curve (Percent Stenosis) Core Lab Data, Total Population Lesions (N=140).

CORE LAB DATA - TOTAL POPULATION LESIONS (N=140)



iii. Site Angiographic Data - Total Population

Angiographic Percent Stenosis

	Mean
Pre-PTCA (N=228 Lesions)	86.6±12.5*
Post-PTCA (N=228 Lesions)	19.7±15.4*

*Standard deviation

iv. Core Lab Angiographic Data - Total Population

	Mean % Stenosis	MLD (mm)
Pre-PTCA (N=140 Lesions)	75.5±11.0*	0.67±0.33*
Post-PTCA (N=140 Lesions)	23.4±2.2*	2.1±0.42*

*Standard Deviation

4. Follow-up Results

Follow-up studies consisted of telephone contact, office visits or hospital examinations. Follow-up was completed at 2 months. Telephone follow-up data were collected by nurses at the investigational site. The following history and physical information were collected: Clinical evidence of restenosis, interim complications including CABG, MI, death, repeat intervention and any other adverse clinical event. Hospital follow-up included angiographic study when medically indicated in addition to the information listed above.

Two-month Follow-up General Status
(There are 19 patients with no two month follow-up available.)

PATIENTS		145	
TYPE OF FOLLOW UP		N	(%)
Outpatient		43	(29.7)
Inpatient		14	(9.7)
Telephone Interview		82	(56.6)
Letter		6	(4.1)
RESTENOSIS	N	(%)	95% C.I.
Clinical evidence of restenosis	19	13.1	8.08-19.70
BY: Recurrent Angina	13	9.0	4.86-14.84
Newly Positive Stress Test	3	2.1	0.43-5.93
>50% Stenosis on follow-up angiogram	15	10.3	5.91-16.49

TWO MONTH FOLLOW-UP ANGIOGRAPHY	N
No. of patients with follow-up angiography	26
No. of lesions with restenosis	11
Information not available	1

TWO MONTH FOLLOW-UP CLINICAL COMPLICATIONS

	N	(%)	95% C.I.
NONE	134	92.4	86.83-96.15
CORONARY OCCLUSION	0	0.0	0.00-2.04
HEMATOMA	0	0.0	0.00-2.04
NON Q MI	0	0.0	0.00-2.04
CABG	1	0.7	0.02-3.78
Q MI	0	0.0	0.00-2.04
DEATH	0	0.0	0.00-2.04
REPEAT PTCA OR INTERVENTION	9	6.2	2.88-11.46
OTHER†	1	0.7	0.02-3.78

† Pseudoaneurysm of groin.

5. Summary of Results of Clinical Studies

a.	Acute Success	n/N	(%)	95% CI
i.	LESIONS			
	Acute Clinical Success (Lesions Treated with Device First)	191/202	94.6	90.6-97.3
	Acute Technical & Clinical Success for Lesions Treated with Device First	185/202	91.6	86.9-95.0
	Acute Technical & Clinical Success for Lesions Treated with Device Only	162/202	80.2	74.0-85.5
ii.	POPULATION			
	Procedure Success (Total population)	155/164	94.5	89.8-97.5
	Procedure Success (LaCrosse™ First Population)	138/147	93.9	88.8-97.2
	Procedure Success (Stand-alone population)	119/147	81.0	73.7-87.0
b.	Acute Complications			
	Major Cardiac Events			
	Death	0/164	0	0.00-1.81
	Q MI	1/164	0.6	0.02-3.25
	CABG	1/164	0.6	0.02-3.25
	Repeat Intervention	2/164	1.2	0.15-4.34
	Any Event	4/164	2.4	0.67-6.1
	Patients free of any acute complications:	139/164		84.8% 95% CI=79.3-89.9
c.	Follow-up Complications			
	Death	0/145	0	0.00-2.04
	Q MI	0/145	0	0.00-2.04
	CABG	1/145	0.7	0.02-3.78
	Repeat Intervention	9/145	6.2	2.88-11.46
	Any Event	10/145	6.9	3.36-12.32

XI. Conclusions Drawn from Studies

The results of the laboratory and animal testing demonstrate that the PAS LaCrosse™ PTCA catheter has the appropriate physical and performance characteristics for its intended use, as stated in the labeling. The biocompatibility tests demonstrate that the material used in the device are biocompatible for short term blood contact. The clinical study conducted indicates with reasonable assurance that the LaCrosse™ PTCA catheter is safe and effective for the treatment of patients with coronary artery disease.

XII. Panel Recommendations

Pursuant to section 515(f)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to The Circulatory Support Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel.

XIII. FDA Decision

The company was in compliance with the Good Manufacturing Practices (GMP) regulations 21CFR Part 820.

XIV. Approval Specifications

Continued approval of the device is contingent upon the submission of post-approval reports to the Food and Drug Administration as described in the Conditions of Approval enclosed in the approval order.

PAS LaCrosse™ PTCA Catheter
Package Insert

I. Device Name

PAS LaCrosse™ PTCA Catheter is a percutaneous transluminal coronary angioplasty catheter.

II. Description

The PAS LaCrosse™ PTCA Catheter is a double lumen coaxial catheter with a balloon near the distal tip. The catheter is constructed from two coaxially aligned tubings. The first (inner) lumen is made of a polyvinylidene fluoride (PVDF) polymer. The second (outer) lumen is composed of two tubings joined together. The proximal tubing is made of polyvinylidene fluoride (PVDF) and is joined to a polyolefin (distal) tubing. The distal portion of the polyolefin tubing has a non-elastomeric balloon formed in it. The balloon is designed to expand to a controlled diameter and length at a specific pressure. The distal end of the balloon is attached to the inner lumen with an adhesive joint. The innermember provides a through lumen for guide wire movement. The LaCrosse™ Catheter does not provide for distal dye injection or pressure measurement.

As with other removable guide wire systems, a side-arm adapter attached to the proximal end of the catheter provides access to the lumens. The side port provides access to the outer balloon inflation lumen by means of a luer-lock fitting. Balloon inflation and deflation are accomplished by connecting the side-arm port with an inflation device. The straight-arm port is continuous with the inner lumen of the catheter and provides access for the guide wire. The LaCrosse™ Catheter can be used with any off-the-shelf 0.014 PTCA guide wires.

III. Indications

The PAS LaCrosse™ PTCA Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

IV. Contraindications

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

V. Warnings

- This device is intended for one time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the: "Use Before" date specified on the package.

VI. Precautions

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

- Administer appropriate anticoagulant and coronary vasodilator therapy before inserting the dilatation catheter.

VII. Adverse Effects

Possible adverse effects include, but are not limited to, the following:

death
acute myocardial infarction
total occlusion of the coronary artery or bypass graft
coronary vessel dissection, perforation, rupture or injury
restenosis of the dilated vessel
hemorrhage or hematoma
unstable angina
arrhythmias, including ventricular fibrillation
drug reactions, allergic reaction to contrast medium
hypo/hypertension
infection
coronary artery spasm
arteriovenous fistula
embolism

VIII. Instructions for Use

Prior to angioplasty, all equipment to be used for the procedure, including the dilatation catheter, should be carefully examined to verify proper performance and freedom from damage. It is important that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

A. Preparation of the PAS LaCrosse™ PTCA Catheter

1. Carefully remove the catheter from its container. Slide the protective sheath off balloon and remove the distal pin.
2. To purge air from the catheter, connect a 20 cc luer-lock syringe filled with approximately 5 cc of 50/50 saline/contrast medium to the balloon port of the catheter.
3. Aspirate for 30 seconds, while holding the syringe with the luer-lock end pointed downward.
4. Allow fluid to infuse slowly into the balloon while keeping the balloon portion of the catheter lower than the manifold.
5. Repeat steps 3 and 4 until air bubbles no longer appear in the syringe during the aspiration cycle and the balloon appears completely filled with fluid.
6. Attach a prepared inflation device to the balloon inflation port of the catheter. To avoid the introduction of air into the catheter, be certain that a meniscus of fluid is present in both the catheter balloon port and the inflation device.

B. Testing the Balloon

1. Inflate the balloon with the fluid to the Nominal Diameter Inflation Pressure. Fully deflate the balloon.
2. Flush the wire lumen with heparinized saline. Insert a 0.014" guide wire into the catheter.
3. To keep the balloon fully deflated, close the stopcock of the inflation device while pulling a negative pressure.

C. Inserting and Advancing the Catheter

1. Insert previously flushed introducer, sheath and guide catheter using standard techniques.
2. Provide the patient with the appropriate anticoagulant and/or coronary vasodilator therapy.
3. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Perform baseline coronary arteriography.
4. Retract the guide wire into the tip of the catheter.
5. With the balloon fully deflated, insert the PAS LaCrosse™ PTCA Catheter through the hemostasis valve that is connected to the guide catheter and advance the device approximately 30 cm.
6. Advance the guide wire and dilatation catheter, under fluoroscopy, beyond the tip of the guiding catheter, and select the desired coronary artery.
7. Advance the dilatation catheter over the guide wire and through the stenosis. After crossing the lesion, advance the wire tip 2-6 cm beyond the lesion. The radiopaque balloon marker(s) should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

D. Balloon Inflation

1. Open the stopcock on the inflation device. Inflate the balloon to dilate the lesion using standard PTCA procedures. Deflate by pulling negative on the inflation device.
2. After the first inflation and each subsequent inflation, assess distal coronary blood flow by dye injection through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guide wire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guide wire may be advanced and maintained across the stenosis as the balloon is deflated and/or withdrawn, permitting reperfusion of the distal vessel.
3. Should a significant stenosis persist, inflate the balloon to gradually increasing pressures up to maximum rated pressure or until the stenosis fails to improve with each subsequent inflation. Successive inflations of the balloon should result in dilatation of the stenosis, which is demonstrated by a decrease in the stenosis and increased contrast flow to the distal vessel.

E. Catheter Removal

1. Check the balloon to verify that it is fully deflated, and then close the stopcock of the inflation device to maintain suction. With the balloon deflated, simultaneously withdraw the dilatation catheter and guide wire out of the coronary artery, and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.
2. Carefully withdraw the guiding catheter from the vessel. Aspirate the sheaths, and then flush them with normal saline. Insert a standard angiographic catheter, and perform the post-dilatation arteriography. Remove the catheter and sheath, and achieve hemostasis by compression.

F. Table of Balloon Compliance Data

Balloon Diameter (mm) versus Inflation Pressure (atm)

Pressure (atm)	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm
3	1.78	2.29	2.72	3.21	3.69
4	1.83	2.35	2.79	3.29	3.80
5	1.89	2.40	2.86	3.35	3.90
6	1.94	2.46	2.94	3.44	4.00
7	2.00	2.50	3.00	3.50	4.09
8	2.05	2.55	3.06	3.57	4.17
9	2.11	2.60	3.10	3.62	4.26
10	2.15	2.64	3.15	3.66	4.33
12	2.22	2.71	3.24	3.76	
14	2.28	2.78	3.32	3.86	
16	2.34	2.84			
Nominal Pressure (atm)	7	7	7	7	6
Rated Burst Pressure (atm)	9	9	8	8	6

IX. References

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

Progressive Angioplasty Systems, Inc.
1350 Willow Road, Suite 201
Menlo Park, CA 94025
415-322-5658
[FAX] 415-322-5610

PACKAGE LABEL TEXT FOR ALL SIZE CATHETERS:

Progressive Angioplasty Systems, Inc.
1350 Willow Road Suite 201
Menlo Park, California 94025
415-322-5658

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by or on the order of a physician.

Recyclable Package (With Symbol)

Lot Number
Ch.-B
Numéro de Lot
Número de Lote
Numero di Lotto

Sterilization Date
Sterilisationsdatum
Date de Stérilisation
Fecha de Esterilización
Data de Sterilizzazione

Use Before
Zu Verwenden vor dem
Utiliser Avant
Fecha de Caducidad
Data di Scadenza

Contents 1
Inhalt
Contenu
Contenido
Contenuto

Balloon Diameter
Ballondurchmesser
Diamètre du ballon
Diámetro del balón
ø del palloncino

Balloon Length
Ballonlänge
Long. du ballon
Long. del balón
Lung. del palloncino

Coronary Dilatation Catheter
Dilatationskatheter
Cathéter de dilatation
Catéter de dilatación
Cathetere per dilatazione

PACKAGE LABEL TEXT FOR ALL SIZE CATHETERS (Continued):

Rated Burst Pressure
Maximaler Balloninsufflationsdruck
Pression maximale de gonflage
Presión máxima de hinchado
Pressione massima de gonfiaggio

Max. Guidewire O.D.
Max. F.-Drahtdurchmesser
D.E. max. du guide
D.E. máx. de la guía
D.E. max. della guida

Shaft Diameter
Schaftdurchmesser
Diamètre du corps
Diámetro del cuerpo
Diametro dello stelo

Shaft Length
Schaftlänge
Longueur du corps
Longitud del cuerpo
Lunghezza dello stelo

Catalog Number
Katalog-Nr.
No. de catalogue
No. de catálogo
N° di catalogo

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use if opened or damaged. Store in a dry, cool place. Refer to accompanying instructions for use.

Steril. Sterilisiert mit Äthylenoxid. Pyrogenfrei. Nur zum einmaligen Gebrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschädigten Packungen benutzen. Trocken und kühl Aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé a l'oxyde d'éthylène. Apyrogène. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protector individuel de stérilité avant usage. Détruire l'objet après usage. A conserver dans un endroit frais et sec. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si la caja está abierta o deteriorada. Almacenar en un lugar fresco y seco. Leer las instrucciones antes de su uso.

Sterile. Sterilizzato ad ossido de etilene. Apirogeno. Monouso. Non risterilizzare. Non usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto. Leggere attentamente le istruzioni.

PACKAGE LABEL SIZE SPECIFIC TEXT:

PAS LaCrosse™ PTCA Catheter	
Balloon Diameter	2.0 mm
Balloon Length:	20 mm
Rated Burst Pressure:	9 atm
Max. Guidewire O.D.:	0.014"
Shaft Diameter:	3.0 F
Shaft Length:	135 cm
Catalog Number:	14-2020-135

PAS LaCrosse™ PTCA Catheter	
Balloon Diameter	2.5 mm
Balloon Length:	20 mm
Rated Burst Pressure:	9 atm
Max. Guidewire O.D.:	0.014"
Shaft Diameter:	3.0 F
Shaft Length:	135 cm
Catalog Number:	14-2520-135

PAS LaCrosse™ PTCA Catheter	
Balloon Diameter	3.0 mm
Balloon Length:	20 mm
Rated Burst Pressure:	8 atm
Max. Guidewire O.D.:	0.014"
Shaft Diameter:	3.3 F
Shaft Length:	135 cm
Catalog Number:	14-3020-135

PAS LaCrosse™ PTCA Catheter	
Balloon Diameter	3.5 mm
Balloon Length:	20 mm
Rated Burst Pressure:	8 atm
Max. Guidewire O.D.:	0.014"
Shaft Diameter:	3.7 F
Shaft Length:	135 cm
Catalog Number:	14-3520-135

PACKAGE LABEL SIZE SPECIFIC TEXT (Continued):

PAS LaCrosse™ PTCA Catheter	
Balloon Diameter	4.0 mm
Balloon Length:	20 mm
Rated Burst Pressure:	6 atm
Max. Guidewire O.D.:	0.014"
Shaft Diameter:	3.7 F
Shaft Length:	135 cm
Catalog Number:	14-4020-135